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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,747

12/29/2003

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EXAMINER

BUI, VY Q

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

06/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/748,747	<b>Applicant(s)</b> GRAVETT ET AL.	
	<b>Examiner</b> Vy Q. Bui	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-12,14,17-28,30,70,73,74,76,78,126-128 and 445-447 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 426-429,432,435,438 and 441 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims pending in the application are 1, 3-4,8-12,14,17-28,30,70,73,74,76,78,126-128,426-429,432,435,438,441 and 445-447.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of invention as recited in claims 1-4, 8-12, 14, 17-28, 30, 70, 73, 74, 76, 78, 126-128 and 444-447 in the reply filed on paper 5/2/2008 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 8-11, 17, 19-21, 24, 30, 78, 446-447 are rejected under 35 U.S.C. 102(e) as being anticipated by Hess et al-US 2001/0053931.

As to claims 1-2, 4, 8-11, 17, 19-21, 24, 30, 78, 444, 446-447, Hess-'931 (abstract, paragraphs [0024], [0025], [0029], [30], [31], [42], [46]) discloses a stent 12 and graft 14 combination, with graft 14 made of a silk or silk derivative (paragraph [46], [47], [48], [50]), silk can be coated with a therapeutic agent or drug ([0054]) substantially as recited in the claims. Hess-'931 ([0042]) discloses silk promotes endothelialization and sustain tissue ingrowth thereon. Inherently, silk will induce a fibrotic response to a fibrous tissue as recited in claim 1.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 3, 12, 14, 18-19, 22-23, 25-28, 70, 73-74, 76, 126-128, 445 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al-US 2001/0053931.

As to claims 3, 12, 14, 18-19, 22-23, 25-28, 70, 73-74, 76, 126-128 and 445, Hess-'931 discloses substantially the claimed invention, except for the limitations as recited in the claims. However, these limitations and their benefits to a patient are well known in the art. It would have been obvious to one of ordinary skill in the art to provide such limitations to a Hess-'931 stent-graft so that one can provide the benefits to a patient as one desires.

### ***Response to Arguments***

Applicant's arguments filed 2/6/2009 have been fully considered but they are not persuasive.

The Applicant correctly stated that silk is used in Hess-'931 because silk is biocompatible and less inflammable to the tissue. However, in addition, silk is inherently or well known to cause fibrosis or a fibrotic response. For example, Jensen et al.-6,181,960 B1 (C 4, L 43-45) discloses that silk is well known as a fiber to cause fibrosis.

Because inherently silk will cause a fibrosis or a fibrotic response to a tissue, a silk graft 14 of Hess-'931 will indeed cause a fibrotic response as recited in amended claim 1.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/  
Primary Examiner, Art Unit 3773